

### **REMARKS**

In the Office Action dated May 15, 2008, the Examiner rejected claims 11-13, 15-18, and 20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,200,200 to Veech (“*Veech*”) and rejected claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Veech in view of U.S. Patent No. 5,383,324 to Segers et al. (“*Segers*”). Claims 11-13 and 15-20 are currently pending in this application.

### **REJECTIONS UNDER § 103(a)**

In the Office Action, the Examiner rejected claims 11-13, 15-18, and 20 under 35 U.S.C. § 103(a) as being unpatentable over *Veech*. Applicant respectfully traverses this rejection.

As a preliminary matter, Applicant notes that the Examiner’s statement on page 5 that “[e]xample 1 teaches that sodium pyruvate is mixed with 1 liter of water and charged (filled) into [the] lower compartment of the container and the compartment is sealed” is inconsistent with the Examiner’s statement on page 6 that “[a]lthough, *Veech* does not teach that the particulate mixture to be an aqueous solution[,] it would have been obvious . . . that the particulate mixture could be formulated into an aqueous solution prior to being charged into the lower compartment of the container.” For purposes of this reply, Applicant has assumed that the Examiner’s statement on page 6 was the Examiner’s intended rationale. Applicant has made this determination because example 1 of *Veech* clearly discloses that the sodium pyruvate is charged into the lower compartment in a dry particulate form. For example, *Veech* discloses that “[s]ufficient crystalline sodium pyruvate is measured to provide 5.1 millimoles per liter thereof in a one liter solution of water, and such crystalline material is charged into the chamber 12

of a container as illustrated above in FIGS. 1 and 2. Thereafter, the chamber 12 is sealed and one liter of the solution above prepared is charged into chamber 11 of such container 10 of FIGS. 1 and 2. Thereafter, the chamber 11 is sealed to provide a storage stable container. Subsequently, the tabs 15 are pulled apart separating the fastener strips 14 from engagement from one another and thereby permitting the solution in chamber 11 to become admixed with the **crystalline** sodium pyruvate in chamber 12. The **crystalline** sodium pyruvate readily dissolves in the solution formally contained in chamber 11 so that a single solution results, thereby providing the desired novel redox balanced Ringer's lactate solution which is ready for conventional intravenous administration." (Col. 7, ll. 36-55.) (Emphasis added.) In other words, it is clear from *Veech* that the sodium pyruvate is in a crystalline (i.e., dry) form when it is charged into chamber 12 (not a liquid form as suggested by the Examiner on page 5 of the Office Action). If Applicant misunderstands the Examiner's intended rationale, Applicant requests further clarification on this point.

Returning to the rejection, certain fundamentals of a Section 103 non-obviousness analysis are particularly relevant here. First, "a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention." M.P.E.P. 2141.02(VI), (emphasis added). Furthermore, "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. 2143.01(VI).

Independent claim 11 recites, among other things, "a first predetermined volume of an aqueous sodium bicarbonate component solution . . . and a second predetermined

volume of an aqueous acid component solution.” In the Office Action, the Examiner concedes that “Veech does not teach that the particulate mixture [is] an aqueous solution.” (Office Action at 6.) The Examiner asserts, however, that “it would have been obvious to one of ordinary skill in the art at the time of the instant invention that the particulate mixture could be formulated into an aqueous solution prior to being charged into the lower compartment of the container.” (*Id.*) Applicant respectfully disagrees.

*Veech* teaches that “[a]s those skilled in the art will understand, these fluid compositions employ redox active agents which are in the nature of metabolites and which are normally present in human blood plasma. These agents include (1) metabolizable ketoacid anions which are unstable because of a tendency to decarboxylate and lose carbon dioxide in aqueous solution, (2) metabolizable sulfhydryl amino acids which dimerize and/or oxidize, and (3) dissolved carbon dioxide which escapes from aqueous solutions in which it is dissolved at a concentration above ambient by diffusing into the atmosphere upon standing.” (Col. 1, ll. 34-45.) (Emphasis added.) *Veech* further discloses that “[t]hese characteristics make it very difficult to formulate, package and store fluid systems utilizing these redox active agents.” (Col. 1, ll. 50-52.) (Emphasis added.) To solve these issues, *Veech* discloses methods “for preparing just before administration unit doses of therapeutic solutions which contain redox active unstable and/or diffusable metabolites such as a ketoacid, a sulfhydryl-containing amino acid, or carbon dioxide. The method involves preparing and storing an aqueous solution of stable components which may or may not contain carbon dioxide. **A dry powder comprised of unstable components is also prepared and stored separately.** These separate component compositions are packaged in, for example,

individual chambers of a common scaled container which is so constructed as to permit the opening, by externally applied manual means or the like, of a passageway between such chambers at the time when usage is contemplated. Thus, a fresh solution in desired full dosage form is preparable just befor[e] administration." (Abstract.) (Emphasis added.)

In other words, *Veech*'s solution to the problems discussed in *Veech* is to keep the unstable components in a dry powder form, wherein the dry powder is separated from the stable aqueous solution until just before use. Thus, *Veech* teaches away from "a first predetermined volume of an aqueous sodium bicarbonate component solution . . . and a second predetermined volume of an aqueous acid component solution" (emphasis added), as recited in independent claim 11.

Applicant further submits that formulating the "particulate mixture . . . into an aqueous solution prior to being charged into the lower compartment of the container," as suggested by the Examiner on page 6 of the Office Action, would destroy the principal of operation of *Veech* since *Veech* specifically discloses the importance of maintaining unstable components in a dry form until just before administration.

Accordingly, the Examiner has not established a case of *prima facie* obviousness at least because 1) *Veech* teaches away from the claimed invention and 2) the Examiner's proposed modification destroys the principle of operation of the prior art invention being modified. Therefore, independent claim 11 is allowable over *Veech* and claims 12, 13, and 15-20 are allowable at least due to their dependence from allowable independent claim 11.

Applicant traverses the Examiner's rejection of claim 19 under 35 U.S.C. § 103(a) as being unpatentable over *Veech* in view of *Segers*. The Examiner contends that "Veech lacks the teaching of the multiple compartment flexible bags being overwrapped in a flexible gas-impermeable plastic material. This deficiency is cured by the teachings of *Segers et al.*" (Office Action at 8.) *Segers*, however, does not remedy the deficiencies of *Veech* described above. Specifically, 1) *Veech* teaches away from the claimed invention and 2) the Examiner's proposed modification to *Veech* destroys the principle of operation of *Veech*. Accordingly, *Segers* fails to overcome the above-mentioned deficiencies of *Veech* and claim 19 is allowable over *Veech* in view of *Segers* at least due to its dependence from allowable independent claim 11.

#### **CONCLUSION**

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 10, 2008

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